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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,014	07/03/2003	Richard A. Earl	102258.156US1	5448
25270	7590	01/11/2006	EXAMINER	
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			SACKEY, EBENEZER O	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,014	Applicant(s) EARL ET AL.	
	Examiner? EBENEZER SACEY	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 5-54 and 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

This is in response to applicant's amendment filed 10/19/05.

Claims 1-58 are pending.

Claims 1, 3 and 4 have been amended.

In view of applicant's response filed 10/19/05, the following applies.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Response to Petition

This is in response to the petition under 37 CFR 1.144, filed March 30, 2005, requesting the withdrawal of an improper restriction requirement. It is noted that the petition filed on 03/30/05 has been denied and thus, the restriction requirement has been deemed proper and hence, made final. Contrary to applicant's assertion, **the entire** elected group has been searched.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the office action mailed on 12/30/04 and 06/17/05 respectively.

Response to Amendment

Applicant's arguments filed 10/19/05 have been fully considered but they are not deemed persuasive. Applicants argue that there are 12 working examples of synthesis for compounds that fall within the scope of the linker X in the compound of formula (I). In response, reasoning and evidence has been provided in making the enablement rejections. Additionally, while some of the 12 working examples may support the scope of the elected support matter, they do not support the remaining entire subject matter of formula (I), which is easily in the thousands based on the definition of R_n and X and the various combinations thereof. The fact that NSAID's are widely used for the treatment of pain, inflammation etc., does not necessarily preclude a finding of nonenablement given the lack of test data commensurate in scope with the claims herein. Please note *University of Rochester v. G.D. Searle & Co.* 68 USPQ 2d. 1424 at 1438, where the preparation and screening for 600 compounds was deemed to be undue. Applicant's scope far exceeds this number. Also note MPEP 2164.08(b) which state that claims that read on "---- significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative." See the last two office actions, which was couched in terms of the Forman factors specifically addressed in that decision, the

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breadth of the claims coupled with unpredictability and level of skill in the art were some of the underlying reasons for making the rejection.

Applicants next argue that a Declaration under 37 C.F.R. 1.132 executed by David S. Garvey supports and provides evidence that one of ordinary skill in the art would be able to make the claimed compounds easily (citing Garveys opinion). It must be noted that the Declaration is an opinion being presented presumably to overcome the rejection of record. It is noted in the Declaration that emphasis has been put on compounds of Formula (I) being "pro-drugs" of a well-known compound. However, the Declaration is made without underlying facts to support such a position based on sound reasoning that would persuade those skilled in the art, and thus, is a mere conclusionary statement. The specification says nothing about formula (I) being a pro-drug of a known compound; it only states that therapeutic agents include pro-drugs. Thus, the declarant's remarks made in paragraph 10 are not consistent with the specification. See page 8, line 15. Also note *In re Grunwall*, 203 USPQ 1055 and *In re Buchner*, 18 USPQ 2d. 1331 regarding opinion affidavits. Also note the following quote taken from *In re Cauvallito* 127 USPQ 202 which was cited in *In re Surrey*, 151 USPQ 724 at page 730, "----where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all or substantially all of them are useful." Also note that compounds as diverse as the various R_n groups (various ring systems) not to mention the various X groups claimed herein have not been shown to share the instantly disclosed NSAID's activity.

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It must be noted that the method of use claims will not be rejoined with the compound claims because the method claims are not commensurate in scope with the compound claims.

Allowable Subject Matter

This application will be in condition for allowance when the following formal matters are complied with:

1. When the presence of non-elected subject matter in the claims are cancelled and when R_n has been limited to compound number 12 and X is as stated in the prior office action i.e., variables number 4-5, 7-9, 14, 27-28 and 32-33 now listed in claim 1 as numbers 1-10 respectively.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704.

The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
January 9, 2006



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600



TAOFIQ SOLOLA
PRIMARY EXAMINER

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